DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service d1827b

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 28, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 31

Arnold M. Suresky
President
Shara Laboratories, Inc.
248 East Town Line Road
Wautoma, Wisconsin 54982

Dear Mr. Suresky:

The Food and Drug Administration (FDA) conducted an inspection of your nutrient supplement manufacturing facility in Wautoma, WI, on February 2, 1998. Five samples were collected for nutrient analysis by FDA laboratories and were identified by sample numbers 98-561-985/989.

Sample 98-561-985 is a [redacted] Calcium, Magnesium and Zinc nutrient supplement, Lot no. 7348. Analysis of this sample reveals serious violations of the Federal Food, Drug and Cosmetic Act (the Act):

1. Calcium levels are less than 50% of that claimed on the label.
2. Magnesium levels are less than 23% of that claimed on the label.

These laboratory findings cause the [redacted] Calcium, Magnesium and Zinc supplement to be adulterated according to Section 402(b)(1) of the Act in that a food shall be deemed to be adulterated if any valuable constituent has been in

whole or in part omitted or abstracted therefrom. This [redacted] Calcium, Magnesium and Zinc supplement is also misbranded according to Section 403(a) of the Act in that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular.

Review of your file indicates the only post-inspectional correspondence has been from FDA to you with a copy of the February 2, 1998, Establishment Inspection Report.

You should take prompt action to correct these violations. Failure to promptly correct these violations of the Act may result in regulatory action being initiated by FDA without further notice and may include product seizure and/or injunction.

Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations with your entire product line. If corrective action cannot be completed within 15 working days, state the reason and the time within which the corrections will be completed.

Your reply and any questions you may have should be directed to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

TPN/ccl